



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/375,169	08/16/99	AITA	C 26767-1000

IM22/0706

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EXAMINER

MCNEIL, J

ART UNIT

PAPER NUMBER

1775

DATE MAILED:

07/06/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/375,169

Applicant(s)

Alta et al

Examiner

Jennifer McNeil

Group Art Unit

1775

☒ Responsive to communication(s) filed on Mar 7, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-30 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-30 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: Page 1, line 9 states "...cardiovascular account for a major portion of such deaths...". Cardiovascular what?

Page 2, line 14: "god" should be --good--.

Page 3, lines 17-18, and page 4, line 1 states that the "swellable component is a hydrate or hydroxide compound such as aluminum hydroxide...". This is an incorrect statement because the swellable component is the nitride and the compound formed is the hydrate or hydroxide.

Page 9, line 12: "believe" should be --believed--.

Page 10, line 10 states "The architectural parameters." This is a sentence fragment.

Appropriate correction is required.

Claim Objections

2. Claims 2, 4, 5, and 28 are objected to because of the following informalities: Claim 2 should read --protective coating of claim 1 further including--; Claim 4, line 2, "form" should be --forms--; Claim 5, line 3, "components" should be --compounds--. Appropriate correction is required. Claim 28, line 2, should read --thereof and having--.

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Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 3 recites the limitation "the inner layers" in line 3. It should read --the said at least one inner layer is selected--. Claim 14 recites the limitation "the first module". Claim 15 recites the limitation "the second module". Claim 16 recites the limitation "the third module". There is insufficient antecedent basis for this limitation in the claim.

Claim 1 states "formed of" which implies unknown process limitations and renders the claim indefinite.

Claim 6 depends from claim 5 which states that the outer layer is alumina, zirconia, or hafnia. It is unclear how this layer would then be of AlN, ZrN, or HfN. Should claim 5 state "the group consisting of aluminum, zirconium, or hafnium compounds?"

Claim 9 refers to a bilayer of zirconia and alumina. It is unclear as to whether the zirconia and alumina are in the same layer and the bilayer is multiple layers of this dual compositional layer or if the bilayer is alternating alumina and zirconia. The same holds for claim 10. Claims 17, 18, 21, and 27 also refer to bilayers in which it is unclear as to the compositions being in the same

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layers and repeated or if the compositions alternate in layers. From the specification and drawings it seems that the bilayers are alternating compositions of alumina, zirconia, and titania. Please clarify.

Claims 9 and 10 refer to a bilayer but does not allude to the placement of this bilayer with respect to the other layers already present.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-6, 11, 12, 17, 18, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Schulz et al (US 5,246,787). Schulz et al teach an instrument with a wear resistant hard coating for working or processing organic materials and is also suitable as implants for the human body including a basic steel body, a transition layer, a separating layer, and a hard coating layer. The hard coating layer may be TiN, or compounds of nitrogen with zirconium or hafnium or mixtures thereof. The separating layer is aluminum oxide or may be an oxide of titanium, zirconium, or hafnium or mixtures thereof. The transition layer gradually changes from aluminum at the surface of the body to aluminum oxide at the surface of the intermediate layer. The separating and transition layers provide a plurality of ceramic bilayers between the body and the

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hard coating (see column 1, lines 52-60; column 2, lines 53-68; column 3, lines 1-3; column 4, lines 57-60; column 5, lines 31-38; column 6, lines 1-68, column 7, lines 1-2).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 7, 8, and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulz et al (5,246,787) in view of Armini et al (US 5,674,293). Schulz et al teach a wear resistant hard coating for instruments used in organic settings as mentioned above where the hard coating has a thickness of 3 microns and the separating layers has a thickness of 0.5-5 microns. Schulz et al do not teach additional thicknesses which may be used. Armini et al teach coated orthopaedic implant components having a hard coating of zirconium oxide (zirconia) applied to a metallic substrate where there are multiple layers of the zirconia applied. The thickness of the coating is 5-5000 Angstroms thick and provides improved wear characteristics. (see column 2, lines 16-19, 54-67; column 3, line 1; column 7, lines 49-55). It would have been obvious to one of ordinary skill in the art at the time of the invention to apply the coatings of Schulz et al with a thickness taught by Armini et al to provide a coating with adequate thicknesses for wear resistance while conserving deposition amounts.

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10. Claims 19, 20, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulz et al (US 5,246,787) in view of Davidas (US 4,326,305). Schulz et al teach a wear resistant hard coating for instruments used in organic settings as mentioned above but does not include aluminum nitride as a choice for the hard coating. Davidas teaches artifacts usable in-vivo having a metal substrate with a coating of AlN having a thickness of 100 angstroms to 0.5 microns. The AlN coating is insulating and prevents oxidation and corrosion of the metal substrate (see column 1, lines 56-63; column 2, lines 52-62). It would have been obvious to one of ordinary skill in the art at the time of the invention to use a protective coating of AlN as taught by Davidas in place of the TiN coating of Schulz et al to provide a coating which serves to insulate the substrate and prevents oxidation and corrosion.

Allowable Subject Matter

11. Claims 9 and 10 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

12. Claims 21-27 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

13. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record does not teach or render obvious an intracorporeal implant comprising a substrate having a protective coating thereon, the protective coating comprising a plurality of

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modules; a first module comprising a number of bilayers comprising alternating layers of zirconia and alumina wherein the number of bilayers is greater than 1; a second module disposed on the first module comprising a number of bilayers comprising alternating layers of zirconia and titania wherein the number of bilayers is greater than 1; and a third modules disposed on the second module and comprises a compound capable of forming a hydrate or hydroxide compound upon contact with an oxygen containing environment.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Patents to Davidson, Taylor, Dorfman et al, Armini et al, Bunker, Meletis, Buechel et al, Sioshansi et al, and Shimamune et al, and non-patent literature of Meinert et al, Piattelli et al, and Kurzweg et al teach coatings with biocompatibility.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer McNeil whose telephone number is (703) 305-0553. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Jones, can be reached at (703) 308-3822.

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communications with the PTO that are not for entry into the file of this application. This will expedite processing of your papers. The fax number for this Group are (703) 305-3599 for "Official" faxes and (703) 3055436 for "Unofficial" faxes.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0661.



Jennifer McNeil
Patent Examiner
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TIMOTHY M. SPEER
PRIMARY EXAMINER